NOT FOR PUBLICATION **FILED UNDER SEAL**

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ALTANA PHARMA AG and WYETH, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., et al., Defendants.	Civil Action No. 04-2355 (JLL) **OPINION**

LINARES, District Judge.

This matter comes before the Court by way of Plaintiffs Altana Pharma AG and Wyeth (collectively "Plaintiffs")'s motion *in limine* seeking to exclude the following evidence pursuant to Fed. R. Evid. 702 and 403: (1) Dr. Ryan Sullivan's opinion on bundling;[1] (2) portions of Dr. Jeffrey Leitzinger's opinions concerning Plaintiffs' lost profits claims; (3) Dr. James Malackowski and Dr. Frank Bernatowicz's respective opinions on reasonable royalties; and (4) Dr. Mitchell Schubert's opinion regarding the interchangeability of various proton-pump inhibitors ("PPI")s. For the reasons set forth below, Plaintiffs' motion is **denied** in its entirety.

I. BACKGROUND

Because the Court has extensively set forth the facts of this case in numerous summary judgment opinions, only those facts specifically pertinent to the instant motion are discussed below.

[1] By letter dated May 1, 2013, the parties advised this Court that the portion of Plaintiff's motion seeking to exclude Dr. Sullivan's "bundling" opinion is moot in light of Defendants' agreement not to enter any evidence regarding "bundling." (CM/ECF No. 1322.) Accordingly, Plaintiffs' motion to exclude Dr. Sullivan's "bundling" opinion is denied as moot.

A. Dr. Jeffrey Leitzinger's Opinions Concerning Plaintiffs' Lost Profit Claims

Dr. Leitzinger is an economist whom Defendant Sun asked to review the opinions of Plaintiffs' expert, Dr. Christopher Vellturo, regarding Plaintiffs' entitlement to lost profits as a result of Sun's infringement of the '579 patent. In Dr. Leitzinger's opinion, "Dr. Vellturo's calculation of lost profit damages attributable to Sun fundamentally errs in its failure to properly assess losses that were reasonably caused by Sun's infringement." (CM/ECF No. 1274-4 at 4, ¶ 7.) Specifically, Dr. Leitzinger opines that Dr. Vellturo's analysis is flawed because it ignores that Teva's infringing generic and Wyeth's own generic were already in the marketplace at the time that Sun launched its product. (*Id.* at 9, ¶ 72.) Consequently, Dr. Leitzinger opines that the lost profits Dr. Vellturo "attributes to Sun are vastly overstated." (*Id.* at 4, ¶ 7.) Additionally, Dr. Leitzinger asserts that "Dr. Vellturo's calculations of overall lost profit amounts . . . are based upon inflated projections of Protonix sales volumes and prices that would have existed but for infringement." (*Id.* at 4-5, ¶ 7.)

B. Dr. James Malackowski and Frank Bernatowicz Opinions Concerning Plaintiffs Reasonable Royalty Claims

Dr. Malackowski and Dr. Bernatowicz are, respectively, Defendants Teva and Sun's reasonable royalty experts. Both experts critique Dr. Vellturo's opinion on reasonable royalties, and base their opinions, in large part, on their review of pantoprazole licensing agreements.

C. Dr. Schubert's Opinion Regarding the Interchangeability of Various PPIs

Dr. Schubert is a physician specializing in gastroenterology. He has served as Chief of Gastroenterology at the McGuire Veterans Affairs Medical Center since 1999, and treats approximately 50-60 patients per week in his clinical practice. (*See* CM/ECF No. 1316-6 at 3, ¶ 6.) Dr. Schubert is also a professor at Virginia Commonwealth University's Medical College, where he teaches gastroenterology to medical students, interns, residents, fellows, and other

gastroenterologists. (*See* CM/ECF No. 1316 at 21.) He also serves as associate-editor of two gastroenterology-related publications—*Digestive Diseases & Sciences* and *Current Opinion in Gastroenterology*. (CM/ECF No. 1316-6 at 2, ¶ 7.)

Teva and Sun retained Dr. Schubert to render an opinion on the interchangeability of PPIs and factors that motivate physicians' PPI-prescribing decisions. (*Id.* at 4, ¶ 10.) Dr. Schubert is expected to testify that when generic pantoprazole entered the market in December 2007, it was already known that "PPIs are clinically equivalent and therapeutically interchangeable. (*Id.* ¶ 12.) Dr. Schubert is also expected to testify that "a predominant factor" in a physician's prescription choice is "[c]ost to the patient (and how it is controlled by [third-party payers]." (*Id.* ¶ 13.) Dr. Schubert bases his conclusions on his training and experience, and his review of medical literature. (*See generally id.*)

II. LEGAL STANDARD

A. General Standard for Deciding Motions *In Limine*[2]

District Courts have broad discretion "in determining the admissibility of evidence under the Federal Rules." *See United States v. Abel*, 469 U.S. 45, 54 (1984). Courts may exercise this discretion to rule on motions *in limine* "to narrow the evidentiary issues for trial and to eliminate unnecessary trial interruptions." *Bradley v. Pittsburgh Bd. of Educ.*, 913 F.2d 1064, 1069 (3d Cir. 1990). It is generally appropriate, however, for courts to reserve judgment on a motion *in limine* until trial. *See, e.g., Kraemer v. Franklin & Marshall College*, No. 95-0020, 1995 U.S. Dist. LEXIS 17093, at *3-4 (E.D. Pa. Nov. 15, 1995) ("The Court declines to rule on whether to exclude . . . testimony before it has been placed into a specific context at trial."); *see also*

[2] Under Federal Circuit precedent, regional circuit law governs evidentiary questions. *See, e.g., Meyer Intellectual Props. Ltd. v. Bodum, Inc.*, 690 F.3d 1354, 1371 (Fed. Cir. 2012) ("We review the district court's decision to exclude evidence under the law of the relevant circuit."). Accordingly, Third Circuit precedent guides this Court's evidentiary determinations.

Hawthorne Partners v. AT&T Technologies, Inc., 831 F. Supp. 1398, 1400 (N.D. Ill. 1993) ("This court has the power to exclude evidence in limine only when evidence is clearly inadmissible on all potential grounds").

B. Standard for Admissibility of Expert Testimony

The admissibility of expert testimony is governed by Fed. R. Evid. 702, which provides as follows:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) The expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) The testimony is based on sufficient facts or data;
>
> (c) The testimony is the product of reliable principles and methods; and
>
> (d) The expert has reliably applied the principles and methods to the facts of the case.

The Third Circuit has held that Rule 702 "embodies a trilogy of restrictions on expert testimony: qualification, reliability and fit." *Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003) (citations omitted). To satisfy the qualification requirement, a witness must "possess specialized expertise." *Id.* at 404. This requirement is interpreted liberally; "a broad range of knowledge, skills, and training qualify an expert as such." *In re Paoli R.R. Yard Pcb Litig.*, 35 F.3d 717, 741 (3d Cir. 1994). To be reliable, there must be a "link between the facts [underlying the expert's opinion] and the conclusion." *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 291 (3d Cir. 2012); *see also Kumho Tire*, 526 U.S. 137, 157 (1999) (observing that courts are not required "to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the

expert") (internal citations omitted). Finally, the question as to whether an expert's proffered testimony is a fit is one of relevance that requires the court to determine whether the proffered testimony "will aid the jury in resolving a factual dispute." *See Lauria v. AMTRAK*, 145 F.3d 593, 599-600 (3d Cir. 1998) (quoting *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 591 (1993)).

It is well settled that district courts must serve a "gatekeeping function" to ensure that an expert's testimony satisfies the requirements of Rule 702. *See, e.g., Daubert*, 509 U.S. at 592-95; *Kumho Tire Co.*, 526 U.S. at 141. In performing this function, courts must be mindful that Rule 702 "has a liberal policy of admissibility." *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008). Indeed, the Third Circuit has observed that the standard for admissibility "is not intended to be a high one." *Oddi v. Ford Motor Co.*, 234 F.3d 136, 145 (3d Cir. 2000). The proponent of expert testimony need not prove that its expert is correct, but that the expert's "opinion is based on valid reasoning and a reliable methodology." *Id.* at 146. "The analysis of conclusions themselves is for the trier of fact when the expert is subject to cross-examination. *Id.*; *see also ZF Meritor*, 696 F.3d at 290 (holding that mere existence of evidence in the record that contradicted expert's conclusion was no basis to exclude expert's testimony).

C. Standard for Exclusion of Testimony under Rule 403

Even if relevant, expert testimony may be excluded under Rule 403. *See, e.g., Daubert*, 509 U.S. at 595. Rule 403 allows district courts to exclude relevant evidence "if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403. "Pretrial Rule 403 exclusions should rarely be granted." *In re Paoli R. Yard PCB Litig.*, 916 F.2d 829, 859-60 (3d Cir. 1990) ("In sum, we hold

that in order to exclude evidence under Rule 403 at the pretrial stage, a court must have a record complete enough on the point at issue to be considered a virtual surrogate for a trial record."). *Id.* at 859.

III. DISCUSSION

The Court will now turn to the merits of Plaintiffs' motion seeking to exclude (1) Dr. Leitzinger's opinions concerning Plaintiffs' lost profits claims; (2) Dr. James Malackowski and Dr. Frank Bernatowicz's respective opinions on reasonable royalties; and (3) Dr. Mitchell Schubert's opinion regarding the interchangeability of various PPIs.

1. Plaintiffs' Motion as to Dr. Leitzinger

Plaintiffs seek to preclude Dr. Leitzinger from testifying about (1) his lost profits calculations premised on the notion that all of Sun's sales would have been made by Wyeth's own generic and (2) his critique of Dr. Vellturo's analysis of the market demand for Protonix.

a. Admissibility of Dr. Leitzinger's Lost Profits Calculations Attributing Plaintiffs' Lost Profits to Sales Lost to Wyeth's Own Generic

Plaintiffs object to the admissibility of Dr. Leitzinger's lost profit calculations on the bases that Dr. Leitzinger (1) has not sponsored his calculations as his own opinion and (2) has conceded that his methodology in performing these calculations is inconsistent with economic principles. (*See* CM/ECF No. 1265 at 21-24.) Specifically, Plaintiffs argue that Dr. Leitzinger's lost profit calculations are inadmissible because he has not sponsored said calculations as the lost profit damages "that could or should or are attributable to Sun." (*Id.* at 22.)

Sun refutes the accuracy of Plaintiffs' assertion that Dr. Leitzinger does not sponsor his calculations relating to lost profits as his own opinion. (CM/ECF No. 1316 at 10.) According to Sun, "Plaintiffs' assertion that Dr. Leitzinger 'does not sponsor' his rebuttal calculation is unfounded as the calculation assumes a but-for world that Dr. Vellturo never acknowledges – a

but-for world that has both brand and generic pantoprazole on the market." (*Id.*) Sun further asserts that "Dr. Leitzinger did not make this calculation because he believes that 100% of Sun's sales would have been interchangeable to Wyeth's AG in the proper but-for world," but "as a rebuttal calculation to demonstrate the significant economic impact of Dr. Vellturo's more lucrative selection of a but-for world that contains only the brand pantoprazole product, Protonix." (*Id.* at 11.)

As this Court has observed in prior summary judgment decisions in connection with this case, determining how the market would have looked but for Defendants' infringement is a factual question for the jury. Fundamental fairness dictates that Sun be entitled to challenge Dr. Vellturo's opinions on lost profit damages by eliciting testimony from Dr. Leitzinger pertaining to his own lost profit calculations. Plaintiffs may attempt to expose flaws in Dr. Leitzinger's calculations at trial. The mere existence of any such flaws, however, does not warrant exclusion of references to Dr. Leitzinger's lost profit calculations at this time. *See, e.g., Stecyk v. Bell Helicopter Textron, Inc.*, 295 F.3d 408, 414-15 (3d Cir. 2002) ("A party confronted with an adverse expert witness who has sufficient, though perhaps not overwhelming, facts and assumptions as the basis for his opinion can highlight those weaknesses through effective cross-examination); *see also United States v. Mitchell*, 365 F.3d 215, 244 (3d Cir. 2004) ("As long as an expert's scientific testimony rests upon 'good grounds, based on what is known,' it should be tested by the adversary process—competing expert testimony and active cross-examination—rather than excluded from jurors' scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies.") (quoting *Ruiz-Troche v. Pepsi Cola Bottling Co.*, 161 F.3d 77, 85 (1st Cir. 1998)).

b. Admissibility of Dr. Leitzinger's Critique of Dr. Vellturo's Analysis of the Market Demand for Protonix

Dr. Vellturo's lost profits analysis is based on the four factors set forth in *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152 (6th Cir. 1978). These *Panduit* factors are: "(1) demand for the patented product, (2) absence of acceptable noninfringing substitutes, (3) [] manufacturing and marketing capability to exploit the demand, and (4) the amount of the profit [the patent owner] would have made." *Panduit*, 575 F.2d at 1156. In Dr. Leitzinger's opinion, Dr. Vellturo's analysis of the first *Panduit* factor – demand for patented product – is flawed because it fails to distinguish between demand for the patented product and demand for the patented technology. According to Dr. Leitzinger, "marketing and low prices were the driving forces behind sales of Protonix and not safety or efficacy tied to the '579 patent." (CM/ECF No. 1265-1 at 283, ¶ 29.)

Plaintiffs argue that Dr. Leitzinger's critique of Dr. Vellturo's analysis of the first *Panduit* factor is "based on a fundamental misapplication of controlling Federal Circuit law." (CM/ECF No. 1265 at 24.) To support this argument, Plaintiffs rely primarily on *DePuy Spine, Inc. v. Medtronic Sofamor Danek*, 567 F.3d 1314 (Fed. Cir. 2009), a case in which the Federal Circuit rejected the notion that the "requisite demand under the first *Panduit* factor is demand for the specific feature . . . that distinguishes the patented product from a noninfringing substitute, not simply demand for the patented product." *DePuy*, 567 F.3d at 1330. The *DePuy* court made clear that the first *Panduit* fact "does not require any allocation of consumer demand among the various limitations recited in a patent claim. . . . [but] simply asks whether demand existed for the 'patented product,' i.e., a product that is 'covered by the patent in suit' or that 'directly competes with the infringing device.'" *Id.* (quoting *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1548-49 (Fed. Cir. 1995) (en banc)).

According to Plaintiffs, Dr. Leitzinger's assertion "that demand for the patented product under *Panduit* can be demonstrated only where the demand for Protonix can be linked to a demand for the claimed feature (the patented compound) that makes Protonix an improvement over other proton-pump inhibitors . . . available in the market" is contrary to Federal Circuit precedent. (*Id.*) Sun, on the other hand, rejects Plaintiffs' characterization of Dr. Leitzinger's opinion as suggesting that establishing a demand for Protonix requires proof of demand for the patented compound that makes Protonix more desirable than other PPIs. (*See* CM/ECF No. 1316 at 8.) Specifically, Sun maintains that Dr. Leitzinger "makes no such statement and does no such thing," but merely "provides an opinion of demand as affected by the relevant economic factors, which include the properties of the pantoprazole compound itself." (*Id.*)

Plaintiffs' argument fails to persuade this Court to exclude Dr. Leitzinger's critique of Dr. Vellturo's opinion for two reasons. First, even if this Court were to accept the correctness of Plaintiffs' interpretation of *DePuy* as holding that demand for the patented product "does not require consideration of the basis for that demand," (*see* CM/ECF No. 1265 at 33), *DePuy* does not categorically prohibit a jury from considering the bases underlying the demand for a patented product for the purpose of determining the extent to which such demand exists. Second, Dr. Vellturo has opined that "there is a clear nexus between the claimed inventions of the '579 patent and the success" of Protonix, Wyeth's own generic, and Teva and Sun's generic pantoprazole. (CM/ECF No. 1316-2 ¶ 136.) Thus, it is appropriate to admit Dr. Leitzinger's rebuttal opinion concerning the extent to which demand for the claimed inventions of the '579 patent drove demand for Protonix, as said opinion will assist the trier of fact in understanding the extent to which Dr. Vellturo has established that such a demand existed.

2. Plaintiffs' Motion as to Dr. Malackowski and Dr. Bernatowicz

There is no dispute that the minimum amount of damages to which Plaintiffs are entitled is a reasonable royalty. *See* 35 U.S.C. § 284; *Bandag, Inc. v. Gerrard Tire Co.*, 704 F.2d 1578, 1583 (Fed. Cir. 1983) ("A reasonable royalty . . . is . . . the floor below which damages shall not fall."). In their respective analyses, Dr. Malackowski and Dr. Bernatowicz apply the hypothetical negotiation framework set forth in *Georgia-Pacific Corp. v. United States Plywood Corp.*, 318 F. Supp. 1116 (S.D.N.Y. 1970). In so doing, both experts rely on actual pantoprazole licenses negotiated by Plaintiffs. (*See* CM/ECF No. 1316-13 ¶¶ 20-21, 39, 45; CM/ECF No. 1309-2 at 35, ¶ 11.3.15.)

Plaintiffs argue that Dr. Malackowski and Dr. Bernatowicz's respective opinions on reasonable royalties are inadmissible because the licensing agreements these experts reviewed "are not sufficiently comparable to the hypothetical licenses to the '579 patent that Plaintiffs would negotiate with Teva and Sun." (CM/ECF No. 1265 at 36.) Specifically, Plaintiffs argue that "each of the licenses on which Mr. Bernatowicz and Mr. Malackowski rely have critical – and disqualifying – differences in scope, time, geography, and economic circumstances to the hypothetical negotiations in this case." (CM/ECF No. *Id.* at 31.)

Plaintiffs' argument does not compel this Court to exclude either Dr. Malackowski or Dr. Bernatowicz's opinions at this time. The extent to which the licenses upon which these experts relied render their opinions inaccurate is a question for the jury. Indeed, the Federal Circuit has recently affirmed that disagreements over an expert's reliance on license agreements as benchmarks for determining a reasonable royalty in a patent infringement case "go to the weight to be afforded the testimony and not its admissibility." *ActiveVideo Networks, Inc. v. Verizon Communs., Inc.*, 694 F.3d 1312, 1333 (Fed. Cir. 2012) ("The degree of comparability of the . . . license agreements as well as any failure on the part of [the patentee's] expert to control for

certain variables are factual issues best addressed by cross examination and not by exclusion."); *see also i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 854 (Fed. Cir. 2010) (holding that a party's quarrel with the facts the damages expert used go to the weight, not admissibility, of the expert's opinion). Accordingly, the Court will not exclude these experts' respective opinions based on their reliance on licensing agreements which Plaintiffs contend are not instructive on the issue of reasonable royalties. Nevertheless, Plaintiffs are free to attempt to expose the flaws they believe exist in Dr. Malackowski and Bernatowicz's respective analyses at trial.

3. Plaintiffs' Motion as to Dr. Schubert

Plaintiffs argue that Dr. Schubert's opinions are inadmissible because "they are based entirely on his own views and experience and fail to survey or otherwise take into account the views of the broader community of PPI-prescribing physicians." (CM/ECF No. 1265 at 48.) Specifically, Plaintiffs argue that Dr. Schubert's opinions are inadmissible because he did not "study physician preferences, prescribing patterns, or switching habits with regard to PPIs." (*Id.*) Plaintiffs also maintain that Dr. Schubert's opinions should be excluded because they ignore "conflicting views as to the safety of certain PPI alternatives to Protonix." (*Id.* at 51.)

It is well settled that an expert may base his opinions on his experience in his specialized field. *See, e.g., Schneider*, 320 F.3d at 399-400 (holding that Magistrate Judge abused discretion in excluding experts' testimony regarding medical standard of care where testimony was based on "considerable professional experience" and knowledge of the "standard of care in the medical field"); *see also Ellison v. United States*, 753 F. Supp. 2d 468, 485 (E.D. Pa. 2010) ("The Court notes, as an initial matter, that the Third Circuit recognized in *Schneider* that a standard of care opinion may be reliable even in the absence of medical literature on point."); *Forest Labs., Inc. v. Ivex Pharms., Inc.*, 237 F.R.D. 106, 111 (D. Del. 2006) (overruling objection to expert's

opinion regarding prescribing habits of psychiatrists because opinion was based on expert's "experience in writing prescriptions himself, as well as supervising others who write prescriptions").

In light of Dr. Schubert's experiences as a practicing gastroenterologist, teacher of gastroenterology, and associate-editor of two gastroenterology-related publications, the Court is satisfied that Dr. Schubert is qualified to opine on the interchangeability of PPIs and on physicians' practices with respect to prescribing PPIs. Plaintiffs' objection to Dr. Schubert's opinion, at bottom, goes to the weight the jury should afford his testimony, not to its admissibility. Accordingly, this Court declines to exclude Dr. Schubert's opinions at this time. *See, e.g., Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."); *see also Stecyk*, 295 F.3d at 414-15; *Voilas v. General Motors Corp.*, 73 F. Supp. 2d 452, 461-62 (D.N.J. 1999) ("[T]he perceived flaws in an expert's testimony often should be treated as matters properly to be tested in the crucible of the adversarial system, not as the basis for truncating that process.") (citations and internal quotation marks omitted).

IV. CONCLUSION

For the foregoing reasons, Plaintiffs' motion is denied in its entirety. An appropriate order follows.

Dated: 14 of May 2013.

JOSE L. LINARES
U.S. DISTRICT JUDGE